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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Larson & Anderson, LLC
P.O. BOX 4928
DILLON, CO 80435

EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,507	SPANGENBERG ET AL.	
	Examiner	Art Unit	
	YONG D. PAK	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30,31,33,35,40-45,49-54,56 and 58-71* is/are pending in the application.

4a) Of the above claim(s) *43-45,49-54,56 and 64-71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-31, 33, 35, 40-42, and 58-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 October 2006* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/7/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/AU04/00493.

The preliminary amendment filed on October 14, 2005, canceling claims 1-29 and adding claims 57, has been entered. The preliminary amendment filed on October 10, 2006, amending claims 32-34 and 55-57, has been entered. The amendment filed on January 22, 2009, amending claims 30-31, 33, , 35, 40, 45, 50-53, and 56, canceling claims 32, 34, 36-39, 46-48, 55, and 57 and adding claims 58-71, has been entered. No new matter has been entered.

Claims 30-31, 33, 35, 40-45, 49-54, 56, and 58-71 are pending. Claims 43-45, 49-54, 56, and 64-71 are withdrawn. Claims 30-31, 33, 35, 40-42, and 58-63 are under consideration.

Election/Restrictions

Applicant's election with traverse of Group I (claims 30-42) with an election of SEQ ID NO:271 in the reply filed on September 25, 2008 is acknowledged. The traversal is on the ground(s) that the method claims and peptide claims have common special technical feature, MDH or MDH-like sequences from clover and this feature is not disclosed in the reference cited (Tesfaye et al). This is not found persuasive because the technical feature linking groups I-V is not limited to MDH or MDH-like polypeptide from clover, but a variant of MDH or MDH-like polypeptides. Further, the DNA molecule of Group I can encode a polypeptide not having the structure of the peptide of Group V or used by the method claims. For a DNA and protein group to

share a special technical feature, claims drawn to the DNA must be DNA sequences that encode the structure of the protein in the claims drawn to the protein (see PCT administrative instructions Example 17).

The requirement is still deemed proper and is therefore made FINAL.

Newly submitted claims 64-71 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the special technical feature of Group I is not required for the method of claims 64-71. Therefore, unity of invention is lacking.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 43-45, 49-54, 56, and 64-71 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 42, 59, and 63 are partially directed to non-elected inventions (plant, plant seed or other plant part). For examination purposes, the Examiner will only examine the elected invention, a plant cell comprising a construct.

Claim for Foreign Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 7, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claims 30-31 are objected to because of the following informalities:

Claims 30-31 recites the phrase "Trifolium" and "Trifolium repens" which should be italicized.

Claims 31, 35, 40-42 and 58-63 are objected to because of the following informalities:

Claims 31, 35, 40-42 and 58-63 are objected for the recitation of "A nucleic acid..", "a nucleic acid..", "A construct..", or "a construct'. Since the nucleic acids and constructs are dependent claims, it is suggested that the claims be amended "The nucleic acid", for example.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 and claims 31, 35, 40-42, 58-59, and 61-63 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the term "MDH-like". The metes and bounds of the term in the context of the claim are unclear. It is unclear as to the respective structure(s) and/or function(s) that is/are meant to be encompassed by the term. The terms encompass many different activities and therefore is outside the scope of the invention. A perusal of the specification did not provide the Examiner with a specific definition for the above terms. Therefore, it is not clear to the Examiner either from the specification or from the claim as to what specific activities of the polypeptide are encompassed in "MDH-like" polypeptides. Examiner requests clarification of the above terms.

Claims 30 and 33 and claims 31, 35, 40-42, and 58-63 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30 and 33 recite the phrase "functionally active". The metes and bounds of the phrase in the context of the above claims are not clear to the Examiner. The phrase encompasses many different functions and activities, such as enzymatic activity and ability to illicit antibodies, which can be considered as "functionally active" and therefore is outside the scope of the invention. A perusal of the specification did not provide the Examiner with a specific definition for the above phrase. Therefore, it is not clear to the Examiner either from the specification or from the claim as to what specific

activities/functions are encompassed in "functionally active". Examiner requests clarification of the above phrase. For examination purposes, the above phrase has been interpreted as polypeptides having any function or activity.

Claims 33 and 58 and claims 59 and 60 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 and 58 recite the phrase "shown in". The metes and bounds of the phrase in the context of the claims are not clear. It is not clear to the Examiner if the recited nucleic acid sequence has the nucleic acid sequence of SEQ ID NO: or is a representative member of a genus. Examiner suggests amending the phrase as "the nucleic acid sequence of SEQ ID NO:".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-31, 33, 35, and 40-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to **(A)** polynucleotide encoding MDH, MDH-like polypeptide, or a functionally active fragment or variant of MDH or MDH-like polypeptide, from a clover; **(B)** polynucleotide of (A) which is from white clover (*T. repens*); **(C)** polynucleotides which are complements of SEQ ID NO:271; **(D)** antisense sequences to SEQ ID:271 or the polynucleotides of (C); **(E)** polynucleotides that are functionally active fragments or variants of the polynucleotides of (C) or (D); **(F)** RNA sequences corresponding to the sequences of (C), (D) or (E); and **(G)** construct comprising said polynucleotide of (A), (B), (C), (D), (E) or (F) and plant cell comprising said construct.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." The examiner has broadly interpreted "MDH-like polypeptide" to encompass polypeptides having any activity. The examiner has broadly interpreted "complements", "antisenses" and "RNA" to encompass any nucleic acids, as little as two nucleic acids, that are complementary to SEQ ID NO:271. The examiner has broadly interpreted "functionally active" to encompass polypeptides having any function. Therefore, the polypeptides of the claims encompass to **(A)** polynucleotide encoding (1) MDH isolated from any or all sources, including any or all variants, mutants, or recombinants thereof, (2) polypeptides having unknown structure and unknown function, or (3) fragments or variants of (1) or (2) and having unknown function; **(B)** polynucleotide of (A) which is from white clover (*T. repens*); **(C)** any or all polynucleotides, as little as two nucleic acids, which are complements of SEQ ID NO:271; **(D)** any antisense sequences, as little as two nucleic

acids, to SEQ ID:271 or the polynucleotides of (C); **(E)** any or all polynucleotides that are fragments or variants of the polynucleotides of (C) or (D) and having unknown function; **(F)** RNA sequences, as little as two nucleic acids, corresponding to the sequences of (C), (D) or (E); and **(G)** construct comprising said polynucleotide of (A), (B), (C), (D), (E) or (F) and plant cell comprising said construct.

Therefore, the claims are drawn to a genus comprising polynucleotides having unknown structure and/or unknown function.

In *University of Calfornia v. Eli Lilly & Co.,* 43 USPQZd 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, (or) chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the

genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The recitation of "MDH" fails to provide a sufficient description of the claimed genus of proteins as it merely describes the functional features of the genus without providing any definition of the structural features of the species within the genus. The CAFC in UC California v. Eli Lilly, (43 USPQ2d 1398) stated that: "in claims to genetic material, however a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus." Similarly with the claimed genus of polynucleotides encoding "erythrose reductase" proteins, the functional definition of the genus does not provide any structural information commonly possessed by members of the genus which distinguish the protein species within the genus from other proteins such that one can visualize or recognize the identity of the members of the genus.

The claims are drawn to polynucleotides having unknown structure, encompassing polynucleotides encoding mutants, fragments and variants of any or all polypeptides having MDH activity that are isolated from any or all sources, any *Trifolium* species or *T. repens*. The specification only describes a polynucleotide of SEQ ID

NO:271 encoding a polypeptide having MDH activity or the full complement of SEQ ID NO:271, vector comprising said polynucleotide, and a plant cell comprising said vector. While MPEP 2163 acknowledges that in certain situations "one species adequately supports a genus," it also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." In view of the widely variant species encompassed by the genus, the one example is not enough and does not constitute a representative number of species to describe the whole genus of polynucleotides having unknown structure, and there is no evidence on the record of the relationship between the structure of the polynucleotide of SEQ ID NO:271 and the structure of any or all variants, recombinant and mutants of SEQ ID NO:271 or any or all MDH isolated from any or all sources, any *Trifolium* species or *T. repens*. Therefore, the specification fails to describe a representative species of the genus.

The claims are also drawn to many polynucleotides encoding functionally unrelated polypeptides encompassed within the scope of these clams, including partial sequences, resulting in a substantial variation within the genus. The genus of these polynucleotides comprise a large variable genus encompassing many different polynucleotides encoding polypeptides having different activity or no activity or unknown activity. The specification only describes a polynucleotide of SEQ ID NO:271 encoding a polypeptide having MDH activity or the full complement of SEQ ID NO:271, vector comprising said polynucleotide, and a plant cell comprising said vector. While MPEP 2163 acknowledges that in certain situations "one species adequately supports a

genus," it also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." In view of the widely variant species encompassed by the genus, this one example is not enough and does not constitute a representative number of species to describe the whole genus of polynucleotides encoding polypeptides having unknown structure and/or unknown function. The specification fails to describe additional representative species of the polynucleotides by any identifying characteristics or properties of the encoded polypeptides, for which no predictability of function is apparent. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 30-31, 33, 35, and 40-42.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 30-31, 33, 35, and 40-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide of SEQ ID NO:271 encoding a polypeptide having MDH activity or the full complement of SEQ ID NO:271, vector comprising said polynucleotide, and a plant cell comprising said vector, does not reasonably provide enablement for a polynucleotide having unknown structure and/or unknown function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to **(A)** polynucleotide encoding MDH, MDH-like polypeptide, or a functionally active fragment or variant of MDH or MDH-like polypeptide, from a clover; **(B)** polynucleotide of (A) which is from white clover (*T. repens*); **(C)** polynucleotides which are complements of SEQ ID NO:271; **(D)** antisense sequences to SEQ ID:271 or the polynucleotides of (C); **(E)** polynucleotides that are functionally active fragments or variants of the polynucleotides of (C) or (D); **(F)** RNA sequences corresponding to the sequences of (C), (D) or (E); and **(G)** construct

comprising said polynucleotide of (A), (B), (C), (D), (E) or (F) and plant cell comprising said construct.

The breadth of the claims.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." The examiner has broadly interpreted "MDH-like polypeptide" to encompass polypeptides having any activity. The examiner has broadly interpreted "complements", "antisenses" and "RNA" to encompass any nucleic acids, as little as two nucleic acids, that are complementary to SEQ ID NO:271. The examiner has broadly interpreted "functionally active" to encompass polypeptides having any function. Therefore, the polypeptides of the claims encompass to **(A)** polynucleotide encoding (1) MDH isolated from any or all sources, including any or all variants, mutants, or recombinants thereof, (2) polypeptides having unknown structure and unknown function, or (3) fragments or variants of (1) or (2) and having unknown function; **(B)** polynucleotide of (A) which is from white clover (*T. repens*); **(C)** any or all polynucleotides, as little as two nucleic acids, which are complements of SEQ ID NO:271; **(D)** any antisense sequences, as little as two nucleic acids, to SEQ ID:271 or the polynucleotides of (C); **(E)** any or all polynucleotides that are fragments or variants of the polynucleotides of (C) or (D) and having unknown function; **(F)** RNA sequences, as little as two nucleic acids, corresponding to the sequences of (C), (D) or (E); and **(G)** construct comprising said polynucleotide of (A), (B), (C), (D), (E) or (F) and plant cell comprising said construct.

Therefore, the claims are drawn to polynucleotides having unknown structure and/or unknown function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides of virtually any structure and/or function or polypeptides/fragments having virtually any structure and/or function. In the instant case, the specification a polynucleotide of SEQ ID NO:271 encoding a polypeptide having MDH activity or the full complement of SEQ ID NO:271, vector comprising said polynucleotide, and a plant cell comprising said vector.

The quantity of experimentation required to practice the claimed invention based on the teachings of the specification.

While enzyme isolation techniques, recombinant and mutagenesis techniques were known in the art at the time of the invention, e.g. hybridization or mutagenesis, and it is routine in the art to screen for variants comprising multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within the encoded protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. Furthermore, while the skilled artisan can produce variants of the polynucleotide of SEQ ID NO:271 having the recited structural characteristics using well-known and widely

used techniques in the art, the amount of experimentation required is not routine due to the fact that the number of species encompassed by the claims is extremely large.

In the absence of: (a) rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function and (b) a correlation between structure and MDH activity, the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. One of skill in the art would have to test these infinite possible polypeptides to determine (1) which ones have MDH activity, (2) the specific substrates targeted by such proteins and (3) how to use those polypeptides encompasses by the claims which do not have MDH activity. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, as is the case herein, the specification must provide a reasonable amount of guidance which respect to the direction in which the experimentation should proceed so that a reasonable number of species can be selected for testing. In view of the fact that such guidance has not been provided in the instant specification, it would require undue experimentation to enable the full scope of the claims.

The state of prior art, the relative skill of those in the art, and predictability or unpredictability of the art.

Since the amino acid sequence of the encoded protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant

of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. In the instant case, neither the specification or the art provide a correlation between structure and activity such that one of skill in the art can envision the structure of any polypeptides having the same biological function as that of the polypeptide encoded by SEQ ID NO:271 or predict the function of a polypeptide from its primary structure. In addition, the art does not provide any teaching or guidance as to (1) which amino acids within the polypeptides encoded by SEQ ID NO: 271 or MDH can be modified and which ones are conserved such that one of skill in the art can make the recited polynucleotides encoding polypeptides having the same enzymatic activity as that of the polypeptide encoded by SEQ ID NO:271, (2) which segments of the polypeptide encoded by SEQ ID NO:271 or MDH are essential for activity, and (3) the general tolerance of MDH proteins to structural modifications and the extent of such tolerance. The art clearly teaches that changes in a protein's amino acid sequence to obtain the desired activity without any guidance/knowledge as to which amino acids in a protein are required for that activity is highly unpredictable. At the time of the invention there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity. For example, Branden et al. (Introduction to Protein Structure, Garland Publishing Inc., New York, page 247, 1991.) teach that (1) protein engineers are frequently surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes, (2) the often surprising results obtained by

experiments where single mutations are made reveal how little is known about the rules of protein stability, and (3) the difficulties in designing de novo stable proteins with specific functions.

Further, the function of a polypeptide cannot be predicted from its structure and the specification does not teach how to use polypeptides having any function or having no activity. The quantity of experimentation in this area is extremely large since there is significant variability in the activity of the polynucleotides in the claims. It would require significant study to identify the actual function of the encoded polypeptides and identifying a use for the encoded polypeptide would be an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Further, the art is extremely unpredictable with regard to protein function in the absence of realizable information regarding its activity. Even very similar proteins may have every different functions. In the current case, where no specific information is known regarding the function, it is entirely unpredictable what function and activity will be found for the protein. The prior art does not resolve this ambiguity, since no prior art activity is identified for the encoded polypeptides.

The amount of direction or guidance presented and the existence of working examples.

The specification discloses only a polynucleotide of SEQ ID NO:271 encoding a polypeptide having MDH activity or the full complement of SEQ ID NO:271, vector

comprising said polynucleotide, and a plant cell comprising said vector. However, the speciation fails to provide any information as to (1) specific substrates associated with the MDH encoded by SEQ ID NO:271, (2) structural elements required in a polypeptide having MDH activity, or (3) which are the structural elements in MDH or the polypeptide encode by SEQ ID NO:271 that are essential to MDH activity. No correlation between structure and function of having MDH activity has been presented. There is no information or guidance as to which amino acid residues in the polypeptides encoded by SEQ ID NO:271 can be modified and which ones are to be conserved to create a polypeptide displaying the same activity as that of the polypeptides of SEQ ID NO:271.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability of the prior art in regard to structural changes and their effect on function and the lack of knowledge about a correlation between structure and function, an undue experimentation would be necessary one having ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides having the desired biological characteristics recited in the claim are unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30, 33, 35, and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Tesfaye et al.

Claims 30, 33, 35, and 40-42 are drawn to **(A)** polynucleotide encoding MDH; **(B)** polynucleotides that are functionally active variants of SEQ ID NO:271; and **(C)** construct comprising said polynucleotide of (A) or (B) and promoter and terminator and a plant cell comprising said construct.

Tesfaye et al. (Plant Physiology – form PTO-1449) discloses a polynucleotide encoding MDH, which are functionally active variants of SEQ ID NO:271 and a construct comprising said polynucleotide, promoter and terminator, and plant cell comprising said construct (pages 1837-1838). Therefore, the reference of Tesfaye et al. anticipates claims 30, 33, 35, and 40-42.

Claims 30, 31, 33, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Tesfaye et al.

Claims 30 and 33 drawn to **(A)** a polynucleotide encoding MDH-like polypeptide or functionally active variants of a MDH-like polypeptide, wherein said polynucleotide is from white clover (*T. repens*) and **(B)** polynucleotides that are functionally active

variants of SEQ ID NO:271. It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." The examiner has broadly interpreted "MDH-like polypeptide" to encompass polypeptides having any activity. The examiner has broadly interpreted "functionally active" to encompass polypeptides having any function.

Ellison et al. (Nucleic Acids Res. 1990 Aug 25;18(16):4913 – form PTO-892) discloses a polynucleotide encoding a dehydrogenase, which are functionally active variants of a MDH-like polypeptide or the polypeptide encoded by SEQ ID NO:271 (page 4913). Therefore, the reference of Ellison et al. anticipates claims 30, 31, 33, and 35.

Conclusion

Claims 30-31, 33, 35, 40-42 and 58-63 are rejected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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/Yong D Pak/
Primary Examiner, Art Unit 1652